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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte TAKAO ABE, HIROSHI MATSUNAGA,  
ADO MIHIRA, CHISATO SATO, HIDEKI USHIROGOCHI,  
KOICHI SATO, TSUYOSHI TAKASAKI,  
ARANAPAKAM MUDUMBAI VENKATESAN,  
and TAREK SUHAYL MANSOUR

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Appeal 2010-010445  
Application 10/693,315  
Technology Center 1600

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Before DEMETRA J. MILLS, FRANCISCO C. PRATS, and  
JEFFREY N. FREDMAN, Administrative Patent Judges.

PRATS, Administrative Patent Judge.

DECISION ON APPEAL

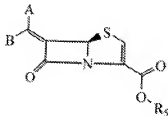
This appeal under 35 U.S.C. § 134 involves claims to a process of making chemical compounds. The Examiner entered a rejection for obviousness-type double patenting.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Appellants' invention is directed to "a novel process for the production of 6-alkylidene penem derivatives that can be important as broad spectrum  $\beta$ -lactamase inhibitors and anti-bacterial agents" (Spec. 1).

Claims 9-11, 13-30, and 32-40 stand rejected and appealed (App. Br. 1).<sup>1</sup> Claim 9 illustrates the appealed subject matter, and recites "[a] process for the preparation of compounds of the formula I



(App. Br. 5.)

Claim 9 specifies an extensive number of different substituents that can be at positions A, B, and R<sub>5</sub> (id. at 5-7), and further recites that said process compris[es]:

(a) condensing an appropriately substituted aldehyde 17

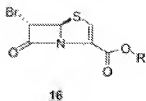


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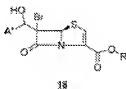
wherein A' is defined as A or B whichever one of A or B is not hydrogen, with 6-bromo-penem derivative of structure 16

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<sup>1</sup> Appeal Brief entered March 3, 2010.

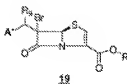


wherein R is p-nitrobenzyl in the presence of a Lewis acid and an organic tertiary amine base, at a temperature of -10°C to -40°C to form an intermediate aldol product 18



wherein A' and R are as defined above;

(b) reacting intermediate 18 with an acid chloride or anhydride, (R<sub>8</sub>)Cl or (R<sub>8</sub>)<sub>2</sub>O, or with tetrahalomethane, C(X<sub>1</sub>)<sub>4</sub>, and triphenyl phosphine, to form intermediate compound 19



wherein R<sub>8</sub> is alkylSO<sub>2</sub>, arylSO<sub>2</sub>, alkylCO, or arylCO; X<sub>1</sub> is Br, I, or Cl; A' and R are as defined above; and R<sub>9</sub> is X<sub>1</sub> or OR<sub>8</sub>; and

(c) converting the intermediate compound 19 to the desired formula I compound by a reductive elimination process, wherein the reductive elimination process is carried out using activated zinc and a phosphate buffer at a pH of about 6.5 to 8.0 and hydrogenating over a catalyst.

The sole rejection before us for review is the Examiner's rejection of claims 9-11, 13-30, and 32-40 "on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 7018997"<sup>2</sup> (Ans. 3-5).

## DISCUSSION

### ISSUE

In rejecting the appealed claims over claims 1-20 of the '997 patent, the Examiner finds that, "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because there is no patentable distinction between the compounds as claimed in the patent, and the method of synthesis, as claimed here" (Final Rejection 3 (entered July 11, 2008) (citing *Mosler Safe & Lock Co. v. Mosler, Bahmann & Co.*, 127 U.S. 354 (1888), and *Ex parte MacAdams*, 206 USPQ 445 (BPAI 1978)).

The Examiner also specifically notes that "no restriction was made in the prosecution of 7018997 between these compounds and their method of synthesis" (Final Rejection 4).

Appellants, in addition to taking issue with the Examiner's interpretation of case law, urge that the Examiner has "erroneously used a rote analysis, rather than applying the proper standard for obviousness type double patenting. In a proper obviousness analysis, the Examiner should consider the differences between the patent claims and the pending claims and determine whether the differences are obvious from the patent claims" (App. Br. 4).

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<sup>2</sup> Aranapakam Mudumbai Venkatesan et al., U.S. Patent No. 7,018,997 B2 (filed May 1, 2003).

Thus, Appellants argue:

In this case, the process steps of the pending claims represent a significant difference from the patent claims; the Examiner has not provided any reasons to support his assertion that these process steps are obvious from the patent claims. Appellants claim a specific multi-step process. In view of the known unpredictability of the chemical arts, it is certainly not obvious from the mere knowledge of the end product.

(Id.)

The Examiner responds that, “[i]nitially, claims to a product, and claims to methods of preparing or using, are not patentably distinct” (Ans. 3 (citing *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003), *In re Boylan*, 392 F.2d 1017 (CCPA 1968); *In re Byck*, 48 F.2d 665 (CCPA 1931), and *In re Freeman*, 166 F.2d 178 (CCPA 1948))).

The Examiner reasons, therefore, that “to show that the compound and process inventions are patentably distinct, applicants must demonstrate that there is an alternative method” of making the patented compounds (Ans. 3-4 (citing *Takeda Pharmaceutical Co., Ltd. v. Dudas*, 511 F.Supp.2d 81 (D.D.C. 2007); *Takeda Pharmaceutical Co., Ltd. v. Doll*, 561 F.3d 1372 (Fed. Cir. 2009); *Phillips Petroleum Co. v. U.S. Steel Corp.*, 604 F.Supp. 555 (D. Del. 1985), *Ex parte Zoss*, 114 USPQ 309 (BPAI 1956), *In re Cady*, 77 F.2d 106 (CCPA 1935), and MPEP § 806.05)).

The Examiner further reasons that, because Appellants have not unequivocally stated and provided supporting evidence that the patented compounds can be made by an alternative process to that recited in the appealed claims, “the standard of specifically setting forth an alternative process has not been met” and “therefore, the rejection is sound” (Ans. 4-5).

The Examiner also concludes that Appellants' urged standard of obviousness-type double patenting, requiring the Examiner to compare the conflicting sets of claims and determine whether the claims at under examination are obvious over the patented claims, "is not the correct standard. Applicants present no case law in defense of their standard for overcoming the nonstatutory obviousness-type double patenting rejection, and the examiner is not aware of any" (id. at 5).

In view of the positions advanced by Appellants and the Examiner, the issue here is whether a prima facie case of obviousness-type double patenting necessarily exists when an applicant presents claims directed to a process of making a patented product, the prima facie case being overcome only by a showing that the patented product can be made by an alternative process to that recited in the claims under examination, or whether, in making a prima facie case of obviousness-type double patenting, the Examiner bears the burden of explaining why an ordinary artisan would have considered the process claims obvious in view of the patented product claims.

#### FINDINGS OF FACT ("*FF*")

1. It is undisputed that claims 1-20 of the '997 patent recite compounds which are produced by the process recited in claims 9-11, 13-30, and 32-40, on appeal herein.
2. It is undisputed that no restriction requirement was made between the compound claims and claims directed to processes of making the compounds during prosecution of the '997 patent.

3. The Examiner finds, and Appellants do not dispute, that the “claimed synthetic process here is in fact the same process as is in the [‘997] patent” (Ans. 5).
4. The Examiner does not advance any evidence to support the finding that the patented product can be made only by the claimed process.
5. Appellants do not advance any evidence to support a finding that the patented product can be made by processes other than the claimed process.
6. The Examiner does not advance any rationale as to why the appealed process claims would have been obvious in view of the patented product claims.

#### ANALYSIS

We conclude that Appellants have the better position.

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

[T]he examiner bears the initial burden . . . of presenting a prima facie case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In evaluating obviousness-type double patenting, the Federal Circuit has explicitly “endorsed an obviousness determination similar to, but not necessarily the same as, that undertaken under 35 U.S.C. § 103 in determining the propriety of a rejection for double patenting.” *In re Braat*, 937 F.2d 589, 592-93 (Fed. Cir. 1991).



Thus, in making an obviousness-type double patenting rejection, the Examiner must show that a claimed invention is “a mere variation of [the patented invention] . . . which would have been obvious to those of ordinary skill in the relevant art . . . [and] there must be some clear evidence to establish why the variation would have been obvious which can properly qualify as ‘prior art.’” In re Kaplan, 789 F.2d 1574, 1579-80 (Fed. Cir. 1986). Accordingly, in Kaplan, the Federal Circuit reversed an obviousness-type double patenting rejection “because there [was] no proper evidence to show that the claim [was] for a mere obvious variation of what is claimed in the Kaplan patent relied on to support the rejection.” Id. at 1581.

Ultimately, therefore, under the “one way” test undisputedly applied in this case, “the examiner asks whether the application claims are obvious over the patent claims.” In re Berg, 140 F.3d 1428, 1432 (Fed. Cir. 1998).

In the instant case the Examiner has provided essentially no evidence or explanation as to why the appealed process claims would have been obvious over claims 1-20 of the ‘997 patent. We therefore conclude that the Examiner has not met the burden required to show that the appealed claims would have been obvious in view of the patented claims. Compare, In re Kaplan, 789 F.2d at 1579-81.

The cases relied on by the Examiner do not persuade us that the rejection should be affirmed. In this regard, we first note that the Examiner appears to seek to rely on a caselaw-derived per se rule to the effect that claims directed to a process of making a particular product are necessarily obvious over the patented product claims, absent some applicant-supplied evidence that an alternative method of making the patented product exists, and that the Examiner therefore need not advance any evidence showing that

the rejected process claims would have been obvious over the patented product claims.

However, as stated in *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995) “reliance on per se rules of obviousness is legally incorrect and must cease.” *Id.* at 1572 (stating that “our precedents do not establish any per se rules of obviousness” and that claims should be examined “in light of all . . . relevant factors, free from any presumed controlling effect” of precedent). Thus, while *Ochiai* may not have involved an obviousness-type double patenting issue, given the analogous nature of the obviousness and obviousness-type double patenting analyses (see, e.g., *Braat*, 937 F.2d at 592-93), we conclude that *Ochiai*’s proscription against per se rejections unsupported by evidence applies equally in this case.

We are also not persuaded that the holdings in *Takeda v. Dudas*, 511 F.Supp.2d 81, or *Takeda v. Doll*, 561 F.3d 1372, discharge the Examiner from the burden of making a prima facie case of unpatentability based on obviousness-type double patenting, nor do they support affirming the Examiner’s rejection.

We first note that *Takeda v. Dudas* seems to reject the premise advanced by the Examiner, as well as the Examiner’s interpretation of *Mosler Safe & Lock Co. v. Mosler, Bahmann & Co.*, 127 U.S. 354: “[o]verall, neither *Mosler* nor any other Supreme Court case broadly prohibits an inventor from receiving a process patent after earlier obtaining a product patent where the inventor could have presented the claims in a single patent. Rather, precedent is to the contrary.” *Takeda v. Dudas* 511 F. Supp.2d at 95.

Nonetheless, we acknowledge the following passage in *Takeda v. Doll*, 561 F.3d at 1375 (emphasis added):

[T]he double patenting doctrine is designed to prevent “unjustified timewise extension of the right to exclude.” In *re Van Ornum*, 686 F.2d 937, 943-44 (CCPA 1982). For instance, the doctrine bars an applicant from obtaining separate patents with separate terms for both a product and process for making *that product, unless the product and process are “patentably distinct.”* See *In re Taylor*, 53 C.C.P.A. 1187, 360 F.2d 232, 234 (1966); *In re Cady*, 22 C.C.P.A. 1190, 77 F.2d 106, 109 (1935) (instructing that “double patenting is not sustainable when the product can be fabricated by processes other than that secured by the issued process patent”) (quotation marks omitted). The PTO’s Manual of Patent Examining Procedure (MPEP) explains that a product and its process are patentably distinct if “the product as claimed can be made by another materially different process.” MPEP § 806.05.

Notably, however, *Takeda v. Doll* did not address the question of whether an examiner may establish a *prima facie* case of obviousness-type double patenting merely by showing that an applicant filed claims to a process of making a patented product. To the contrary, the only issue truly addressed was the “novel legal question . . . ask[ing] if later-developed alternative processes are relevant in the product-process ‘patentably distinct’ inquiry.” *Takeda v. Doll*, 561 F.3d at 1375.

Specifically, in *Takeda v. Dudas*, this Board had affirmed a double patenting rejection, but had explicitly declined to categorize it as an obviousness-type double patenting rejection. See 511 F.Supp.2d at 84. On appeal to the District Court for the District of Columbia, the court granted *Takeda*’s motion for summary judgment and reversed the rejection, finding that *Takeda* had advanced sufficient evidence of alternative methods of

preparation to show patentable distinctness between the previously patented product and the later patented process. *Id.* at 96-97.

Thus, in *Takeda v. Dudas*, since the presence of alternative methods warranted reversal regardless of whether a *prima facie* case had been made, and since the rejection was never explicitly categorized as an obviousness-type double patenting rejection, the court technically never reached the question of whether a *prima facie* case of obviousness-type double patenting could be established merely by showing the existence of an earlier patented product and later-applied-for process claims. Similarly, when the case was appealed to the Federal Circuit, that issue was not addressed. See, generally, *Takeda. v. Doll*, 561 F.3d 1372.

We are therefore not persuaded that the *Takeda* cases compel us to affirm the Examiner's rejection. Nor are we persuaded that *In re Cady*, 77 F.2d 106, compels affirmance.

The *Cady* court ultimately reversed a double patenting rejection based on evidence of an alternative method of making a patented product, as well as evidence that restriction was required during prosecution of the patent. See *id.* at 109. However, the *Cady* decision does not mention obviousness-type double patenting, nor did *Cady* consider whether the process claims at issue would have been obvious in view of previously patented product claims.

Rather, the analysis applied in *Cady* suggests that at that time (1935) the Court of Customs and Patent Appeals considered the double patenting issue involving a patented product and its sole process of making as falling under a same-type double patenting analysis:

It is not, of course, intended to indicate here that there should be any modification of the doctrine stated by this court in the case of *In re Albert C. Fischer*, 57 F.(2d) 369, 370, 19 C. P. A. (Patents) 1077, where we said: 'We think the weight of authority is to the effect that an inventor is only entitled to one patent for one invention, and that he cannot prolong his monopoly by claiming nothing more than the same invention in different language.'

The rule there stated was sound; but, under the circumstances of this case, where the Primary Examiner in requ[i]ring division must have been of the opinion that the inventive distinction between appellant's process and product claims was clear, his decision should not be lightly overruled.

*In re Cady*, 77 F.2d at 109 (emphasis added).

We are also not persuaded that *Phillips Petroleum Co. v. U.S. Steel Corp.*, 604 F.Supp. 555, compels us to affirm the Examiner's rejection. To the contrary, the court in *Phillips* declined to hold the patents in question invalid for obviousness-type double patenting because the defendants had failed to show that either set of allegedly conflicting claims would have been obvious in view of the other set:

Equally important, movants have not, and cannot, make a showing that the process for making polypropylene would have been obvious from the claim of the '851 patent. Movants do not contend, and no record support has been cited for the proposition, that the process of claim 16 could be ferreted out merely from knowledge of the product of the '851 patent. I am therefore not persuaded that the '851 patent should fail under the test for obvious type double patenting.

604 F.Supp. at 569. Thus, in finding no case of obviousness-type double patenting, the *Phillips* court applied the very criterion urged by the Examiner as being an incorrect standard.

We also conclude that *Geneva Pharmaceuticals v. GlaxoSmithKline*, 349 F.3d 1373, *In re Boylan*, 392 F.2d 1017, and *In re Byck*, 48 F.2d 665, are factually distinguishable from the instant case, and therefore do not control the result here. Specifically, unlike the product/process of making situation involved here, *Geneva Pharmaceuticals* involved invalidating claims directed to “nothing more than [the patented product’s] disclosed utility as a method of using the [patented] compound”, 349 F.3d at 1386, where a restriction requirement was insufficient to shield against a holding of double patenting rejection. *Id.* at 1377-82.

In *Boylan*, the court did not decide the issue of obviousness-type double patenting, since a terminal disclaimer had already been filed. See *In re Boylan*, 392 F.2d 1017, 1018; see also *id.* at 1021 (citations omitted):

Where, as here, the subject matter claimed in the application is not the same as subject matter claimed in the patent, . . . questions of whether the two sets of claims ‘overlap,’ or are ‘patentably distinct,’ one from the other, and the like, are of no moment, so long as a terminal disclaimer has been filed.

In *In re Byck*, the claims being rejected were directed to products which the Board had characterized as involving “no invention” as compared to the phenolic condensation product the appellant had already patented. See *In re Byck*, 48 F.2d at 666. The court affirmed the Board, concluding, among other things, that “that the application here in issue does not claim a separate invention from that claimed in the issued patent, but only claims an obvious use of the composition there patented.” *Id.*

Thus, not only do the facts of *Byck* not align with the facts in this case, but the language in *Byck* suggests that the court applied precisely the

obviousness analysis urged by the Examiner as being an incorrect standard for obviousness-type double patenting.

In re Freeman is also distinguishable from the instant fact situation because the patented claims were process claims, whereas the claims subject to the rejection were product claims. See In re Freeman, 166 F.2d 178, 180:

The claims of appellant's patent are process claims, whereas the claims here involved are product claims. However, since the product in each of the appealed claims is defined essentially in terms of the method by which it is made, the fact that the claims of the patent and the application are, technically, in different statutory classes, is not in itself, enough to avoid a rejection on the ground of double patenting.

Thus, we are not persuaded that Freeman's fact situation is sufficiently close to the instant fact situation to be controlling.

We are similarly unpersuaded that the BPAI decisions cited by the Examiner are sufficiently close to the instant situation factually to control our analysis. See Ex Parte Zoss, 114 USPQ 109 (double patenting rejection of product claims reversed); see also, Ex parte MacAdams, 206 USPQ 445, 449 (double patenting rejection entered by Board where claims under examination recited method of using patented composition in which the claimed use "would be so recognized by those skilled in the art, as is apparent from secondary references, [and therefore] not seen to be drawn to a separate and patentably distinct invention").

Lastly, we note the following statement in MPEP § 806.05 (emphasis added):

Where two or more related inventions are claimed, the principal question to be determined in connection with a requirement to restrict or a rejection on the ground of double patenting is whether or not the inventions as claimed are

distinct. If they are distinct, restriction may be proper. If they are not distinct, restriction is never proper. If nondistinct inventions are claimed in separate applications or patents, double patenting must be held, except where the additional applications were filed consonant with a requirement to restrict.

MPEP § 806.05 does not, however, explain how to make an obviousness-type double patenting rejection, or what the requirements are for doing so. Rather, consistent with the discussion herein, MPEP § 804 explains, in relevant part, that the “analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination.” MPEP § 804(B)(1) (citing *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985)).

In sum, the Examiner urges that case law and the MPEP support the proposition that the standard to be applied when evaluating claims for obviousness-type double patenting is not a determination of whether the claims under examination would have been obvious to an ordinary artisan in view of the patented claims. The Examiner does not, however, point to any specific language in any of the cited cases, or in the MPEP, to support that proposition. As seen above, a review of the cited cases and relevant MPEP sections does not support the Examiner’s position.

We wish to reiterate, and make specific note of here, as to the absence of evidence showing the claimed process to be the only way to make the claimed product.

Accordingly, we conclude that, because the Examiner has not adequately explained why the rejected claims would have been obvious in



view of claims 1-20 of '997 patent, the Examiner has not met the burden required to sustain the obviousness-type double patenting rejection. We therefore reverse the Examiner's obviousness-type double patenting rejection of claims 9-11, 13-30, and 32-40 over claims 1-20 of the '997 patent.

REVERSED

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